Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 205

Report Date:04/29/2009

Study Summary

| Laboratory Name | Study Number | Study Start Date | Length of Study in Days | Number of Animals Total and (#/Cage) | Number Surviving and (Mean Life Span) | Maximum Mean Weekly Body Weight | Chemical |
|--|---|--|----------------------------------|--|---|--|---|
| | | | | M | ale | | |
| Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute | 059902704 050517406 059900706 059201306 052000804 | 07/29/02 N/A 05/12/03 02/03/00 03/25/03 | 729 N/A 729 729 729 | 50 (1) 0 (0) 50 (1) 50 (1) 50 (1) | 46(715) 0(0) 43(715) 45(717) 45(712) | 50.0 N/A 48.3 46.1 49.8 | Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract |
| | | | | Fer | nale | | |
| Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute | 059902704 050517406 059900706 059201306 052000804 | 07/29/02 08/20/02 05/12/03 02/03/00 03/25/03 | 732 728 732 734 732 | 50 (5) 50 (5) 50 (5) 50 (5) 50 (5) | 45(698) 41(696) 44(718) 42(706) 40(714) | 50.3 51.8 51.9 45.6 51.0 | Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract |

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 206

| | | | Male | | | | Female | |
|--|-------|----------------------------|-------------|-------------|-------|----------------------------|----------------------------|-------------|
| All Organs: Benign Tumors | | | | | | | | |
| | | 28/50 (56%) 26/50 (52%) | 21/50 (42%) | 28/50 (56%) | | 16/50 (32%) 18/50 (36%) | 16/50 (32%) 18/50 (36%) | 17/50 (34%) |
| verall Incidence | Total | 103/200 (51.5%) | Mean 51.5% | SD 6.61% | Total | 85/250 (34%) | Mean 34% | SD 2% |
| All Organs: Malignant Tumors | ••••• | | | | ••••• | | | |
| | | 24/50 (48%) 15/50 (30%) | 29/50 (58%) | 20/50 (40%) | | 22/50 (44%) 20/50 (40%) | 20/50 (40%) 19/50 (38%) | 13/50 (26%) |
| Overall Incidence | Total | 88/200 (44%) | Mean 44% | SD 11.89% | Total | 94/250 (37.6%) | Mean 37.6% | SD 6.84% |
| #All Organs: Malignant and Benign T | | 40/50 (80%) | | 38/50 (76%) | | 31/50 (62%) | 29/50 (58%) | 26/50 (52%) |
| | | 34/50 (68%) | 39/50 (78%) | (, | | 29/50 (58%) | 32/50 (64%) | (, |
| Overall Incidence | Total | 151/200 (75.5%) | Mean 75.5% | SD 5.26% | Total | 147/250 (58.8%) | Mean 58.8% | SD 4.6% |
| All Organs: Hemangioma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 2/200 (1%) | Mean 1% | SD 2% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| All Organs: Hemangiosarcoma | ••••• | | | | | | | |
| | | 2/50 (4%) 1/50 (2%) | 3/50 (6%) | 2/50 (4%) | | 3/50 (6%) 3/50 (6%) | 1/50 (2%) 2/50 (4%) | 1/50 (2%) |
| Overall Incidence | Total | 8/200 (4%) | Mean 4% | SD 1.63% | Total | 10/250 (4%) | Mean 4% | SD 2% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|---|---------------|---------------------------------------|-----------------------|-----------------------|-------|--|---|------------------------|
| All Organs: | Jomangioma | | | | | | | |
| Hemangiosarcoma or H | nemangioma | 2/50 (4%) | | 2/50 (4%) | | 3/50 (6%) | 1/50 (2%) | 1/50 (2%) |
| | | 1/50 (2%) | 4/50 (8%) | , , | | 3/50 (6%) | 3/50 (6%) | , |
| verall Incidence | Total | 9/200 (4.5%) | Mean 4.5% | SD 2.52% | Total | 11/250 (4.4%) | Mean 4.4% | SD 2.19% |
| All Organs: Histiocytic Sarcoma | | | ••••• | | | | | |
| riistiocytic Sarconia | | 0/50 (0%) | | 0/50 (0%) | | 1/50 (2%) | 2/50 (4%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | , , | | 1/50 (2%) | 1/50 (2%) | , , |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 5/250 (2%) | Mean 2% | SD 1.41% |
| or Undifferentiated Cell | Total | 2/50 (4%) 3/50 (6%) 12/200 (6%) | 6/50 (12%) Mean 6% | 1/50 (2%) SD 4.32% | Total | 5/50 (10%) 7/50 (14%) 36/250 (14.4%) | 7/50 (14%) 11/50 (22%) Mean 14.4% | 6/50 (12%) SD 4.56% |
| All Organs: | | | | | | | | |
| | Malignant NO | 3 | | | | | | |
| Mesothelioma: Benign, | Malignant, NO | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Mesothelioma: Benign, | - | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | , | | 0/50 (0%) | 0/50 (0%) | , |
| Mesothelioma: Benign, | Malignant, NO | 0/50 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | | | 0/50 (0%) SD 0% |
| Mesothelioma: Benign, verall Incidence | Total | 0/50 (0%) 0/50 (0%) | ` , | , | Total | 0/50 (0%) | 0/50 (0%) | , |
| Mesothelioma: Benign, | Total | 0/50 (0%) 0/50 (0%) 0/200 (0%) | ` , | SD 0% | Total | 0/50 (0%) 0/250 (0%) | 0/50 (0%) Mean 0% | SD 0% |
| Mesothelioma: Benign, everall Incidence All Organs: | Total | 0/50 (0%) 0/50 (0%) | ` , | , | Total | 0/50 (0%) | 0/50 (0%) | , |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|---|--------|-------------------------|----------------------|-----------|--------|---------------------------|------------------------|-----------|
| All Organs: Osteoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (00/) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 0/250 (0%) | 0/50 (0%) Mean 0% | SD 0% |
| verali iliciuelice | ı Olai | 0/200 (0/8) | IVICALI 070 | | ı Olai | 0/230 (0/8) | IVICALI 070 | |
| All Organs: Osteosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (09/) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | 0/50 (0%) |
| verall Incidence | Total | 0/50 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 1/250 (0.4%) | 1/50 (2%) Mean 0.4% | SD 0.89% |
| verali iliciaelice | Total | , , | | | | 17230 (0.470) | | OD 0.0070 |
| All Organs: Osteosarcoma or Osteom | ıa | | | | | | | |
| | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Normall Institutes | Tatal | 0/50 (0%) | 0/50 (0%) | CD 00/ | Tatal | 0/50 (0%) | 1/50 (2%) | CD 0.000/ |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| Adrenal Cortex: Adenoma | | | | | | | | |
| | | 0/50 (0%) | | 2/50 (4%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 4/50 (8%) | 1/50 (2%) | | | 0/50 (0%) | 0/50 (0%) | |
| verall Incidence | Total | 7/200 (3.5%) | Mean 3.5% | SD 3.42% | Total | 0/249 (0%) | Mean 0% | SD 0% |
| Adrenal Cortex: Plasma Cell Tumor Maligr | nant | | | | | | | |
| | | 0/50 (0%) | 0/50 (09/) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 0/249 (0%) | 0/50 (0%) Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Control Animal Groups Δι Page: 209

Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

| | | | Male | | | | Female | |
|--|----------------|---|-------------------------|-----------|-------|------------------------|-------------------------|-----------|
| *Adrenal Cortex: Sarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% |
| Adrenal Medulla: Pheochromocytoma Bo | enign | | | | | ••••• | | |
| | | 0/49 (0%) 0/50 (0%) | 1/49 (2%) | 0/50 (0%) | | 0/49 (0%) 0/50 (0%) | 0/49 (0%) 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/198 (0.51%) | Mean 0.51% | SD 1.02% | Total | 0/247 (0%) | Mean 0% | SD 0% |
| Adrenal Medulla: Pheochromocytoma Co | omplex | | | | | | | |
| • | • | 0/49 (0%) 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/49 (0%) 0/50 (0%) | 0/49 (0%) 0/49 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/198 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% |
| Adrenal Medulla: Pheochromocytoma M | alignant | | | | | | | |
| | J | 0/49 (0%) 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 1/49 (2%) 1/50 (2%) | 1/49 (2%) 0/49 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/198 (0%) | Mean 0% | SD 0% | Total | 3/247 (1.21%) | Mean 1.22% | SD 1.11% |
| Adrenal Medulla: | | | | ••••• | | ••••• | | |
| Pheochromocytoma: B | enign, Complex | x, Malignant, NOS 0/49 (0%) 0/50 (0%) | 1/49 (2%) | 0/50 (0%) | | 1/49 (2%) 1/50 (2%) | 1/49 (2%) 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/198 (0.51%) | 1/49 (2%) Mean 0.51% | SD 1.02% | Total | 3/247 (1.21%) | 0/49 (0%) Mean 1.22% | SD 1.11% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE **Strain:** B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|---------------------------------|-------|------------------------|------------|------------|-------|------------------------|------------------------|------------|
| Bone Marrow: Hemangioma | | 0(50 (00/) | | 0/50 (00/) | | 0/50 /00/ | 0/50 /00/3 | 0/40 /05/2 |
| | | 0/50 (0%) 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/199 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% |
| Bone Marrow: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) 1/50 (2%) | 1/49 (2%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/49 (0%) |
| verall Incidence | Total | 2/199 (1.01%) | Mean 1.01% | SD 1.17% | Total | 0/249 (0%) | Mean 0% | SD 0% |
| 3one Marrow: | | | | | | | | |
| Plasma Cell Tumor Malig | gnant | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/49 (0%) |
| verall Incidence | Total | 0/199 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% |
| Bone: | | | ••••• | | | | | |
| Hemangiosarcoma | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/00 (0/0) | | 0/50 (0%) | 0/50 (0%) | 0/30 (0/6) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Bone: Osteoma | | | | | | | | |
| O St. Solina | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

System Page: 211
Animal Groups Report Date: 04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|----------------------------------|-------|-------------------------|----------------------|-----------|-------|-------------------------|------------------------|-----------|
| #Bone: Osteosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| #Bone: Osteosarcoma or Osteom | | | ••••• | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| #Bone: Sarcoma | | | ••••• | | | | | |
| | | 0/50 (0%) | 0/50 (00/) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 0/250 (0%) | 0/50 (0%) Mean 0% | SD 0% |
| *Brain: | | | | | | | ••••• | |
| Meningioma Benign | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| *Brain: | | | | | | | | |
| Meningioma Malignant | | 0/50 (0%) | 0/50 (00/) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 0/250 (0%) | 0/50 (0%) Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology D

Contract/Lab: All Laboratories Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 212

| | | | Male | | | | Female | |
|---|------------|--|------------------------|--------------------|-------|---|--------------------------------------|-----------------------|
| Brain: Meningioma: Benign, Mali | gnant, NOS | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Brain: Schwannoma Malignant | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 0/250 (0%) | 0/50 (0%) Mean 0% | SD 0% |
| Clitoral/Preputial Gland: Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/50 (0%) 1/200 (0.5%) | 1/50 (2%) Mean 0.5% | 0/50 (0%) SD 1% | Total | 0/44 (0%) 0/50 (0%) 0/240 (0%) | 0/49 (0%) 0/47 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Clitoral/Preputial Gland: Carcinoma | | | | | | | | |
| overall Incidence | Total | 0/50 (0%) 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/44 (0%) 0/50 (0%) 1/240 (0.42%) | 1/49 (2%) 0/47 (0%) Mean 0.41% | 0/50 (0%) SD 0.91% |
| Clitoral/Preputial Gland: Carcinoma or Adenoma | | | | | | | | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/50 (0%) 1/200 (0.5%) | 1/50 (2%) Mean 0.5% | 0/50 (0%) SD 1% | Total | 0/44 (0%) 0/50 (0%) 1/240 (0.42%) | 1/49 (2%) 0/47 (0%) Mean 0.41% | 0/50 (0%) SD 0.91% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

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Species: MICE Strain: B6C3F1

Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|--|-------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| Clitoral/Preputial Gland: Hemangioma | | | | | | | | |
| • | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/44 (0%) 0/50 (0%) | 0/49 (0%) 0/47 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/240 (0%) | Mean 0% | SD 0% |
| Clitoral/Preputial Gland: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/44 (0%) 0/50 (0%) | 0/49 (0%) 0/47 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/240 (0%) | Mean 0% | SD 0% |
| Clitoral/Preputial Gland: Squamous Cell Carcinoma | | | | | | | | |
| 1,100 | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/44 (0%) 0/50 (0%) | 0/49 (0%) 0/47 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/240 (0%) | Mean 0% | SD 0% |
| Esophagus: Squamous Cell Carcinoma | | | | | | | | |
| • | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Eye: Sarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

d Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

| | | | Male | | | | Female | |
|---|-------|--------------------------|------------|------------|-------|--------------------------|--------------------------|------------|
| #Harderian Gland: Adenoma | | | | | | | | |
| | | 5/50 (10%) 4/50 (8%) | 5/50 (10%) | 7/50 (14%) | | 7/50 (14%) 6/50 (12%) | 6/50 (12%) 6/50 (12%) | 5/50 (10%) |
| Overall Incidence | Total | 21/200 (10.5%) | Mean 10.5% | SD 2.52% | Total | 30/250 (12%) | Mean 12% | SD 1.41% |
| #Harderian Gland: Carcinoma | | | | | | | | |
| | | 1/50 (2%) 1/50 (2%) | 0/50 (0%) | 2/50 (4%) | | 2/50 (4%) 1/50 (2%) | 1/50 (2%) 2/50 (4%) | 2/50 (4%) |
| Overall Incidence | Total | 4/200 (2%) | Mean 2% | SD 1.63% | Total | 8/250 (3.2%) | Mean 3.2% | SD 1.1% |
| #Harderian Gland: Carcinoma or Adenoma | | | | | | | | |
| | | 5/50 (10%) 5/50 (10%) | 5/50 (10%) | 9/50 (18%) | | 9/50 (18%) 7/50 (14%) | 7/50 (14%) 8/50 (16%) | 7/50 (14%) |
| Overall Incidence | Total | 24/200 (12%) | Mean 12% | SD 4% | Total | 38/250 (15.2%) | Mean 15.2% | SD 1.79% |
| #Harderian Gland: Sarcoma | | | | | | ••••• | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| *Heart: Hemangioma | | | | | | | | |
| • | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Vehicle: FEED

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

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I Groups Report Date: 04/29/2009

Nopo.

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|-------|-------------------------|----------------------|------------|--------|-------------------------|------------------------|------------|
| Heart: Hemangiosarcoma | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| leart: Sarcoma | | 0/50 (00) | | 0/50 (00/) | | 0/50 (00) | 0/50 (00/) | 0/50 (00/) |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| ntestine Large: Cecum: Carcinoma | | | ••••• | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| rerall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| ntestine Large: Cecum: Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/30 (0%) | Mean 0% | SD 0% |
| ntestine Large: Cecum: Leiomyoma | | | | | | | | |
| • | | 0/50 (0%) | 0/50 (00/) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 0/250 (0%) | 0/50 (0%) Mean 0% | SD 0% |
| veran incluence | TULAI | 0/200 (0%) | IVICALI U70 | 3D 070 | i Ulai | 0/200 (0%) | IVICALI U70 | 3D 0% |

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|---|-------|-------------------------|----------------------|-----------|-------|-------------------------|------------------------|-----------|
| Intestine Large: Colon/Rectu Leiomyosarcoma | um: | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Intestine Small: Duodenum: Adenoma | | | | | | | | |
| | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Intestine Small: Duodenum: Carcinoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| ntestine Small: Duodenum: Leiomyosarcoma | ••••• | | | | | | | |
| Loiomyoodrooma | | 0/50 (0%) | 0/50 (00/) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 0/250 (0%) | 0/50 (0%) Mean 0% | SD 0% |
| Intestine Small: Duodenum: Polyp Adenomatous | | | | | •••• | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 1/50 (2%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 217

| | | | Male | | | | Female | |
|--|-------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| #Intestine Small: Ileum: Carcinoma | | | | | | | | |
| | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Intestine Small: Ileum: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Intestine Small: Ileum: Polyp Adenomatous | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Intestine Small: Jejunum: Adenoma | | | | | | ••••• | ••••• | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Intestine Small: Jejunum: Carcinoma | | | | | | ••••• | ••••• | ••••• |
| | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 3/200 (1.5%) | Mean 1.5% | SD 1.91% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 218

| | | | Male | | | | Female | |
|--|-------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| Intestine Small: Jejunum: Hemangiosarcoma | | | | | | | | |
| - | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Intestine Small: Jejunum: Leiomyosarcoma | | | ••••• | | | ••••• | | ••••• |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| Intestine Small: Jejunum: Polyp Adenomatous | | | | ••••• | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Intestine Small: Site Unspeci Adenoma | | | | ••••• | | | | |
| | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Intestine Small: Site Unspeci Carcinoma | | | | | | | | |
| | | 2/50 (4%) 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 4/200 (2%) | Mean 2% | SD 2.31% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: FEED

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| | | | Male | | | | Female | |
|---|-----------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| Intestine Small: Site Unsp Carcinoma or Adenom | | | | | | | | |
| Carollionia of Adenom | ··· | 3/50 (6%) 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 5/200 (2.5%) | Mean 2.5% | SD 3% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| Intestine Small: Site Unsp Hemangiosarcoma | | | | | | | ••••• | |
| - | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Intestine Small: Site Unsp Leiomyosarcoma | pecified: | | | | | | | |
| , | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| Intestine Small: Site Unsp Polyp Adenomatous | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 1/50 (2%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| Islets, Pancreatic: Adenoma | | | | | | | | |
| | | 1/50 (2%) 0/49 (0%) | 0/49 (0%) | 0/49 (0%) | | 0/50 (0%) 0/49 (0%) | 1/50 (2%) 0/49 (0%) | 1/48 (2%) |
| Overall Incidence | Total | 1/197 (0.51%) | Mean 0.5% | SD 1% | Total | 2/246 (0.81%) | Mean 0.82% | SD 1.12% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|--|-------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| Islets, Pancreatic: Carcinoma | | | | | | | | |
| | | 0/50 (0%) 0/49 (0%) | 0/49 (0%) | 0/49 (0%) | | 2/50 (4%) 0/49 (0%) | 0/50 (0%) 0/49 (0%) | 0/48 (0%) |
| Overall Incidence | Total | 0/197 (0%) | Mean 0% | SD 0% | Total | 2/246 (0.81%) | Mean 0.8% | SD 1.79% |
| slets, Pancreatic: Carcinoma or Adenoma | | | | | | | | |
| | | 1/50 (2%) 0/49 (0%) | 0/49 (0%) | 0/49 (0%) | | 2/50 (4%) 0/49 (0%) | 1/50 (2%) 0/49 (0%) | 1/48 (2%) |
| Overall Incidence | Total | 1/197 (0.51%) | Mean 0.5% | SD 1% | Total | 4/246 (1.63%) | Mean 1.62% | SD 1.68% |
| Kidney: Renal Tubule: Adenoma | | | | | | | | |
| | | 2/50 (4%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 2/200 (1%) | Mean 1% | SD 2% | Total | 0/249 (0%) | Mean 0% | SD 0% |
| Kidney: Renal Tubule: Carcinoma | | | | | | ••••• | | ••••• |
| Carcinoma | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/249 (0%) | Mean 0% | SD 0% |
| | | | | | | ••••• | | ••••• |
| Ca. Chiana di Addinina | | 3/50 (6%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 3/200 (1.5%) | Mean 1.5% | SD 3% | Total | 0/49 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: FEED

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| | | | Male | | | | Female | |
|---|-------|------------------------|----------------------|-----------|-------|------------------------|------------------------|-----------|
| *Kidney: Renal Tubule: Hemangioma | | | | | | | | |
| • | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% |
| *Kidney: Renal Tubule: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% |
| *Kidney: Renal Tubule: Plasma Cell Tumor Malig | nant | | | | | | | |
| J | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% |
| *Liver: | | | | ••••• | | ••••• | | |
| Cholangiocarcinoma | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| *Liver: Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (09/) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) | 0/50 (0%) Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 222

| | | | Male | | | | Female | |
|---------------------------------|-------|----------------------------|-------------|-------------|-------|------------------------|------------------------|-----------|
| Liver: Hemangioma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Liver: Hemangiosarcoma | | | | | | | | |
| | | 2/50 (4%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 2/200 (1%) | Mean 1% | SD 2% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Liver: Hepatoblastoma | | | | | | | | ••••• |
| • | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Liver: Hepatocellular Adenoma | ••••• | | | | | | | |
| , | | 21/50 (42%) 17/50 (34%) | 12/50 (24%) | 22/50 (44%) | | 1/50 (2%) 4/50 (8%) | 4/50 (8%) 3/50 (6%) | 3/50 (6%) |
| Overall Incidence | Total | 72/200 (36%) | Mean 36% | SD 9.09% | Total | 15/250 (6%) | Mean 6% | SD 2.45% |
| Liver: Hepatocellular Carcinoma | | | | | ••••• | | | |
| | | 15/50 (30%) 10/50 (20%) | 17/50 (34%) | 8/50 (16%) | | 3/50 (6%) 1/50 (2%) | 1/50 (2%) 0/50 (0%) | 3/50 (6%) |
| Overall Incidence | Total | 50/200 (25%) | Mean 25% | SD 8.41% | Total | 8/250 (3.2%) | Mean 3.2% | SD 2.68% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male **Female** *Liver: Hepatocellular Carcinoma or Hepatoblastoma 15/50 (30%)(18%)3/50 (6%)1/50 (2%)3/50 (6%)(20%) (0%)10/50 17/50 (34%)1/50 (2%)0/50 **Overall Incidence** 51/200 (25.5%) Mean 25.5% SD 7.72% Total 8/250 (3.2%) Mean 3.2% SD 2.68% Total *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 32/50 (64%)(52%)4/50 (8%)4/50 (8%)(12%)23/50 (46%)26/50 (52%)5/50 (10%)3/50 (6%)**Overall Incidence** Mean 53.5% SD 7.55% 22/250 (8.8%)Mean 8.8% SD 2.28% Total 107/200 (53.5%) Total *Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma (64%)26/50 (52%)4/50 (8%)4/50 (8%)6/50 (12%)(46%)26/50 23/50 (52%)5/50 (10%)3/50 (6%)**Overall Incidence** Total 107/200 (53.5%) Mean 53.5% 22/250 (8.8%)Mean 8.8% SD 2.28% SD 7.55% Total *Liver: Hepatocholangiocarcinoma 0/50 (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)(0%)Overall Incidence Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/250 (0%) Mean 0% SD 0% *Liver: Hepatocholangioma 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 224

| | | | Male | | | | Female | |
|------------------------------------|-------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| Liver: Ito Cell Tumor Benign | | | | | | | | |
| no cen rumor berngn | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| iver: Ito Cell Tumor Malignant | | | ••••• | | | | ••••• | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Liver: Plasma Cell Tumor Malign | ant | | | | | | | |
| _ | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| .iver: Sarcoma | | | | | | | | ••••• |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Lung: Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

| | | | Male | | | | Female | |
|--|----------------|---------------------------|-------------|-------------|-------|------------------------|-------------------------|------------|
| *Lung: Alveolar/Bronchiolar A | donoma | | | | | | | |
| Aiveolai/Bioliciliolai Ai | uenoma | 13/50 (26%) 8/50 (16%) | 1/50 (2%) | 4/50 (8%) | | 1/50 (2%) 0/50 (0%) | 5/50 (10%) 1/50 (2%) | 4/50 (8%) |
| Overall Incidence | Total | 26/200 (13%) | Mean 13% | SD 10.39% | Total | 11/250 (4.4%) | Mean 4.4% | SD 4.34% |
| *Lung: Alveolar/Bronchiolar Ca | arcinoma | | | | | | | |
| | | 3/50 (6%) 2/50 (4%) | 10/50 (20%) | 6/50 (12%) | | 1/50 (2%) 3/50 (6%) | 2/50 (4%) 1/50 (2%) | 1/50 (2%) |
| Overall Incidence | Total | 21/200 (10.5%) | Mean 10.5% | SD 7.19% | Total | 8/250 (3.2%) | Mean 3.2% | SD 1.79% |
| *Lung: Alveolar/Bronchiolar Ca Adenoma | arcinoma or Al | veolar/Bronchiolar | | | | | | |
| | | 16/50 (32%) 9/50 (18%) | 11/50 (22%) | 10/50 (20%) | | 2/50 (4%) 3/50 (6%) | 5/50 (10%) 2/50 (4%) | 5/50 (10%) |
| Overall Incidence | Total | 46/200 (23%) | Mean 23% | SD 6.22% | Total | 17/250 (6.8%) | Mean 6.8% | SD 3.03% |
| *Lung: Fibrosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| *Lung: Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

Page: 226

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|--------------------------------------|-------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| *Lung: Hemangiosarcoma | | | | | | | | |
| _ | | 0/50 (0%) 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| *Lung: Plasma Cell Tumor Malign | ant | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| *Lung: Sarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| #Lymph Node: Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| #Lymph Node: Hemangioma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

| | | | Male | | | | Female | |
|--|-------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| #Lymph Node: Hemangiosarcoma | | | | | | | | |
| · | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| #Lymph Node: Plasma Cell Tumor Malign | ant | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| #Lymph Node: Sarcoma | | | | ••••• | | | ••••• | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| #Lymph Node, Bronchial: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| #Lymph Node, Mandibular: Fibrous Histiocytoma | | | | | | | | |
| - | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 228

| | | | Male | | | | Female | |
|--|-------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| Lymph Node, Mandibular: Hemangiosarcoma | | | | | | | | |
| - | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| Lymph Node, Mandibular: Mast Cell Tumor Malignant | | | | | | | | ••••• |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Lymph Node, Mandibular: Plasma Cell Tumor Maligna | nt | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Lymph Node, Mesenteric: Fibrous Histiocytoma | | | | | | | | |
| • | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Lymph Node, Mesenteric: Hemangioma | | | | | ••••• | | | |
| | | 0/50 (0%) 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 229

| | | | Male | | | | Female | |
|--|-------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| Lymph Node, Mesenteric: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Lymph Node, Mesenteric: Plasma Cell Tumor Malig | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| #Mammary Gland: Adenoacanthoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Mammary Gland: | | | | | | | | ••••• |
| Adenoma | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | , , | | 0/50 (0%) | 0/50 (0%) | , , |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Mammary Gland: Carcinoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) 1/50 (2%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 230

| | | | Male | | | | Female | |
|--|----------------|-------------------------|----------------------|------------|-------|------------------------|------------------------|------------|
| Mammary Gland: Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) 1/50 (2%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% |
| Mammary Gland: Fibroadenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| :Mammary Gland: | | | | | ••••• | | | |
| Fibroma, Fibroadenoma | or Adenoma | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Mammary Gland: | | | | | | | | |
| Fibroma, Fibroadenoma | , Carcinoma, o | or Adenoma 0/50 (0%) | | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/30 (0/0) | | 1/50 (2%) | 0/50 (0%) | 0/30 (0/0) |
| overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% |
| Mesentery: Fibrosarcoma | | | | ••••• | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (09/) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) | 0/50 (0%) Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 231 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|--|--------|-------------------------|------------------------|-----------|--------|-------------------------|------------------------|-----------|
| Mesentery: Hemangioma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 1/50 (20/) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 1/200 (0.5%) | 1/50 (2%) Mean 0.5% | SD 1% | Total | 0/50 (0%) 0/250 (0%) | 0/50 (0%) Mean 0% | SD 0% |
| lesentery: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| lesentery: Sarcoma | | | | | | - () | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| erall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| ose: Mast Cell Tumor Malignant | | | | | | | | |
| | | 1/50 (2%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| renell le ei den ee | Tatal | 0/50 (0%) | 0/50 (0%) | CD 40/ | Tatal | 0/50 (0%) | 0/50 (0%) | CD 00/ |
| erall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| ral Cavity (Oral Mucosa, Ton Papilloma Squamous or Pa | | vnx, Tooth, Gingiva): | | | | | | |
| | | 0/50 (0%) | 0/50 (00/) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 0/250 (0%) | 0/50 (0%) Mean 0% | SD 0% |
| Gran molucitos | i otai | 0/200 (0/0) | IVICALI U/0 | 3D 076 | i otal | 0/200 (0/0) | Mean 070 | 30 070 |

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)(0%) 0/50 0/50 (0%)0/50 0/50 0/250 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** 0/200 (0%) SD 0% 0/250 (0%) SD 0% Total Mean 0% Total Mean 0% Choriocarcinoma 0/48 (0%)0/50 (0%)0/49 (0%)(0%) 0/48 0/46 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/241 (0%) *Ovary: Cystadenoma 0/481/50 (2%)3/49 (6%)1/46 2/48 (4%)(2%)**Overall Incidence** Total 7/241 (2.9%) Mean 2.89% SD 2.33% *Ovary: **Fibrous Histiocytoma** 0/48(0%)0/50 (0%)0/49 (0%)(0%)0/48 (0%)0/46 **Overall Incidence** Total 0/241 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

| | Male | | Female |
|--|------|------------------------|----------------------------------|
| *Ovary: Granulosa Cell Tumor Benign | | | |
| Grandiosa Celi Tunior Benign | | 2/48 (4%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Tar | 2/48 (4%) | 0/46 (0%) |
| Overall incidence | Tot | al 4/241 (1.66%) | Mean 1.67% SD 2.28% |
| *Ovary: | | | |
| Granulosa Cell Tumor Malignant | | | |
| | | 1/48 (2%) 0/48 (0%) | 0/50 (0%) 0/49 (0%) 0/46 (0%) |
| Overall Incidence | Tot | ` , | Mean 0.42% SD 0.93% |
| | | | |
| *Ovary: | | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | 3/48 (6%) | 0/50 (0%) 0/49 (0%) |
| | | 2/48 (4%) | 0/46 (0%) |
| Overall Incidence | Tot | al 5/241 (2.07%) | Mean 2.08% SD 2.95% |
| *Overv | | | |
| *Ovary: Hemangioma | | | |
| - | | 0/48 (0%) 0/48 (0%) | 0/50 (0%) 0/49 (0%) 0/46 (0%) |
| Overall Incidence | Tot | ` ' | Mean 0% SD 0% |
| | | ` , | |
| *Ovary: | | | |
| Hemangiosarcoma | | 0/48 (0%) | 0/50 (0%) 0/49 (0%) |
| | | 0/48 (0%) | 0/46 (0%) |
| Overall Incidence | Tot | al 0/241 (0%) | Mean 0% SD 0% |
| | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

Page: 234

Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

| | Male | | | Female | |
|-----------------------------|------|-------|------------------------|------------------------|------------|
| Ovary: | | | | | |
| Leiomyosarcoma | | | 0/48 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | | 0/48 (0%) | 0/46 (0%) | (0,70) |
| verall Incidence | | Total | 0/241 (0%) | Mean 0% | SD 0% |
| lvary: | | | | | |
| Luteoma | | | | | |
| | | | 0/48 (0%) 0/48 (0%) | 0/50 (0%) 0/46 (0%) | 0/49 (0%) |
| Overall Incidence | | Total | 0/241 (0%) | Mean 0% | SD 0% |
| | | | (/ | | |
| Ovary: | | | | | |
| Plasma Cell Tumor Malignant | | | 0/48 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | | 0/48 (0%) | 0/46 (0%) | 0/43 (070) |
| verall Incidence | | Total | 0/241 (0%) | Mean 0% | SD 0% |
| Ovary: | | | | | |
| Teratoma Benign | | | | | |
| | | | 0/48 (0%) 0/48 (0%) | 0/50 (0%) 0/46 (0%) | 0/49 (0%) |
| verall Incidence | | Total | 0/241 (0%) | Mean 0% | SD 0% |
| | | | ` , | | |
| Ovary: | | | | | |
| Teratoma Malignant | | | 0/48 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | | 0/48 (0%) | 0/46 (0%) | 0/43 (0/0) |
| Overall Incidence | | Total | 0/241 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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ups Report Da

Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|---|-------|------------------------|------------|-----------|-------|-------------------------|------------------------|-----------|
| Ovary: Tubulostromal Adenoma | | | | | | | 2/22 (22/) | |
| | | | | | | 0/48 (0%) 0/48 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | | | | | Total | 0/48 (0%) 0/241 (0%) | 0/46 (0%) Mean 0% | SD 0% |
| Pancreas: Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/49 (0%) | 0/49 (0%) | 1/49 (2%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) 0/49 (0%) | 0/48 (0%) |
| Overall Incidence | Total | 1/197 (0.51%) | Mean 0.51% | SD 1.02% | Total | 0/246 (0%) | Mean 0% | SD 0% |
| Pancreas: Carcinoma | | | | | | | | |
| | | 0/50 (0%) 0/49 (0%) | 0/49 (0%) | 0/49 (0%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) 0/49 (0%) | 0/48 (0%) |
| overall Incidence | Total | 0/197 (0%) | Mean 0% | SD 0% | Total | 0/246 (0%) | Mean 0% | SD 0% |
| Pancreas: Carcinoma or Adenoma | | ••••• | | ••••• | | | | •••••• |
| Carcinoma of Adenoma | | 0/50 (0%) 0/49 (0%) | 0/49 (0%) | 1/49 (2%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) 0/49 (0%) | 0/48 (0%) |
| verall Incidence | Total | 1/197 (0.51%) | Mean 0.51% | SD 1.02% | Total | 0/246 (0%) | Mean 0% | SD 0% |
| Pituitary Gland: Pars Distalis o Adenoma | | | | ••••• | | | | ••••• |
| | | 0/48 (0%) 0/49 (0%) | 0/48 (0%) | 0/50 (0%) | | 1/47 (2%) 5/49 (10%) | 2/50 (4%) 2/49 (4%) | 0/50 (0%) |
| Overall Incidence | Total | 0/195 (0%) | Mean 0% | SD 0% | Total | 10/245 (4.08%) | Mean 4.08% | SD 3.81% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 236 Report Date:04/29/2009

| | | | Male | | | | Female | |
|---|------------------|------------------------|-----------|-----------|-------|-------------------------|------------------------|-----------|
| Pituitary Gland: Pars Dista Carcinoma | alis or Unspecif | ied Site: | | | | | | |
| | | 0/48 (0%) 0/49 (0%) | 0/48 (0%) | 0/50 (0%) | | 0/47 (0%) 0/49 (0%) | 0/50 (0%) 0/49 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/195 (0%) | Mean 0% | SD 0% | Total | 0/245 (0%) | Mean 0% | SD 0% |
| Pituitary Gland: Pars Dista Carcinoma or Adenoma | alis or Unspecif | ied Site: | | | ••••• | | | |
| | | 0/48 (0%) 0/49 (0%) | 0/48 (0%) | 0/50 (0%) | | 1/47 (2%) 5/49 (10%) | 2/50 (4%) 2/49 (4%) | 0/50 (0%) |
| Overall Incidence | Total | 0/195 (0%) | Mean 0% | SD 0% | Total | 10/245 (4.08%) | Mean 4.08% | SD 3.81% |
| Pituitary Gland: Pars Inter Adenoma | media: | | | | | | | |
| | | 0/48 (0%) 0/49 (0%) | 0/48 (0%) | 0/50 (0%) | | 1/47 (2%) 0/49 (0%) | 0/50 (0%) 0/49 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/195 (0%) | Mean 0% | SD 0% | Total | 1/245 (0.41%) | Mean 0.43% | SD 0.95% |
| Pituitary Gland: Pars Inter Carcinoma or Adenoma | media: | | | | | | | ••••• |
| | | 0/48 (0%) 0/49 (0%) | 0/48 (0%) | 0/50 (0%) | | 1/47 (2%) 0/49 (0%) | 0/50 (0%) 0/49 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/195 (0%) | Mean 0% | SD 0% | Total | 1/245 (0.41%) | Mean 0.43% | SD 0.95% |
| Prostate: Adenoma | | | | | | | | |
| | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | | |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 237 Report Date:04/29/2009

Contract/Lab: All Laboratories

Route: ORAL

Vehicle: FEED

| | | | Male | | | | Female | |
|--|-------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| *Prostate: Carcinoma or Adenoma | | | | | | | | |
| | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | | |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | | | | |
| *Prostate: Hemangioma | | | | | | | | |
| • | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | | |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | | | | |
| *Salivary Glands: Carcinoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| *Salivary Glands: Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| *Salivary Glands: Mast Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Route: ORAL Vehicle: FEED Page: 238

| | | | Male | | | | Female | |
|--|-------|-------------------------|----------------------|------------|-------|---------------------------|------------------------|-----------|
| #Seminal Vesicle: Adenoma | | 0/50 (00/) | | 0/50 (00/) | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | | |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | | | | |
| #Skeletal Muscle: Fibrosarcoma | | | ••••• | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| #Skeletal Muscle: Hemangiosarcoma | | | ••••• | | | | | |
| , and the second | | 0/50 (0%) 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 2/200 (1%) | Mean 1% | SD 1.15% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| #Skeletal Muscle: | | | | | | | | |
| Myxosarcoma | | 0/50 (0%) | 0/50 (00/) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 0/250 (0%) | 0/50 (0%) Mean 0% | SD 0% |
| #Skeletal Muscle: | | ••••• | ••••• | ••••• | | | | |
| Rhabdomyosarcoma | | 0/50 (0%) | 0/50 (00%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 1/250 (0.4%) | 1/50 (2%) Mean 0.4% | SD 0.89% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: MICE **Strain:** B6C3F1

Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|---|----------------------------|--|----------------------|--------------------|-------|--------------------------------------|-----------------------------------|--------------------|
| #Skeletal Muscle: Rhabdomyosarcoma or R | habdomyom | a | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| #Skeletal Muscle: Sarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| #Skin: Basal Cell Adenoma or Ba Overall Incidence | asosquamou Total | s Tumor Benign 0/50 (0%) 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/50 (0%) 0/250 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Skin: Basal Cell Adenoma, Basa Trichoepithelioma | | Tumor Benign, or | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| Skin: Basal Cell Carcinoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| | | | | | | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|---|----------------------|--|---------------------------------|--------------------|-------|--|--|--------------------|
| #Skin: Basal Cell Carcinoma or Ba NOS) | asosquamo | us Tumor (malignant c | r | | | | | |
| , | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 05.00/ | | 0/50 (0%) | 0/50 (0%) | 00.00 |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Skin: Basal Cell Carcinoma, Basa Tumor (benign, malignant c | | Trichoepithelioma 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| or B), Basal Cell Adenoma, Papilloma, Keratoacanthon | | | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| | Total | 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 1/250 (0.4%) | 0/50 (0%) Mean 0.4% | SD 0.89% |
| | | 0/200 (0%) | Mean 0% | | | 0/50 (0.4%) | Mean 0.4% | |
| Skin: Basosquamous Tumor Ben Overall Incidence | nign Total | 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%) | Mean 0% 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/250 (0.4%) 0/50 (0%) 0/50 (0%) 0/250 (0%) | Mean 0.4% 0/50 (0%) 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Overall Incidence #Skin: Basosquamous Tumor Ben Overall Incidence #Skin: Fibroma | nign Total | 0/200 (0%) ´ 0/50 (0%) 0/50 (0%) 0/200 (0%) | Mean 0% 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/250 (0.4%) 0/50 (0%) 0/50 (0%) 0/250 (0%) | Mean 0.4% 0/50 (0%) 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Skin: Basosquamous Tumor Ben Overall Incidence | nign Total | 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%) | Mean 0% 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/250 (0.4%) 0/50 (0%) 0/50 (0%) 0/250 (0%) | Mean 0.4% 0/50 (0%) 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: MICE **Strain:** B6C3F1

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

| | | | Male | | | | Female | | | |
|--|-------------------------------|--|------------------------|-----------------------|----------------|--|--|-----------------------|--|--|
| #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | | |
| | | 1/50 (2%) 0/50 (0%) | 3/50 (6%) | 0/50 (0%) | | 2/50 (4%) 2/50 (4%) | 5/50 (10%) 3/50 (6%) | 3/50 (6%) | | |
| Overall Incidence | Total | 4/200 (2%) | Mean 2% | SD 2.83% | Total | 15/250 (6%) | Mean 6% | SD 2.45% | | |
| #Skin: Fibrosarcoma | | | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) 1/50 (2%) | 4/50 (8%) 3/50 (6%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 10/250 (4%) | Mean 4% | SD 2.83% | | |
| #Skin: Fibrosarcoma, Sarcom | a. Myxosarcom | a or Fibrous | | | | | | | | |
| #Skin: Fibrosarcoma, Sarcom Histiocytoma | a, Myxosarcom | 1/50 (2%) 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | | 2/50 (4%) 2/50 (4%) | 5/50 (10%) 3/50 (6%) | 3/50 (6%) | | |
| Fibrosarcoma, Sarcom Histiocytoma | a, Myxosarcom Total | 1/50 (2%) | 2/50 (4%) Mean 1.5% | 0/50 (0%) SD 1.91% | Total | | | 3/50 (6%) SD 2.45% | | |
| Fibrosarcoma, Sarcom Histiocytoma Overall Incidence | | 1/50 (2%) 0/50 (0%) | ` , | (111) | Total | 2/50 (4%) | 3/50 (6%) | , | | |
| Fibrosarcoma, Sarcom Histiocytoma Overall Incidence Skin: | | 1/50 (2%) 0/50 (0%) | ` , | (111) | Total | 2/50 (4%) | 3/50 (6%) | , | | |
| Fibrosarcoma, Sarcom Histiocytoma Dverall Incidence Skin: Fibrous Histiocytoma | | 1/50 (2%) 0/50 (0%) 3/200 (1.5%) 1/50 (2%) | Mean `1.5% | SD 1.91% | Total Total | 2/50 (4%) 15/250 (6%) 1/50 (2%) | 3/50 (6%) Mean 6% | SD 2.45% | | |
| Fibrosarcoma, Sarcom Histiocytoma Overall Incidence Skin: Fibrous Histiocytoma Overall Incidence | Total Total | 1/50 (2%) 0/50 (0%) 3/200 (1.5%) 1/50 (2%) 0/50 (0%) | Mean 1.5% | SD 1.91% | | 2/50 (4%) 15/250 (6%) 1/50 (2%) 0/50 (0%) | 3/50 (6%) Mean 6% 0/50 (0%) 0/50 (0%) | SD 2.45% 0/50 (0%) | | |
| Fibrosarcoma, Sarcom Histiocytoma Overall Incidence #Skin: Fibrous Histiocytoma Overall Incidence | Total Total | 1/50 (2%) 0/50 (0%) 3/200 (1.5%) 1/50 (2%) 0/50 (0%) | Mean 1.5% | SD 1.91% | | 2/50 (4%) 15/250 (6%) 1/50 (2%) 0/50 (0%) | 3/50 (6%) Mean 6% 0/50 (0%) 0/50 (0%) | SD 2.45% 0/50 (0%) | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 242

| | | | Male | | | | Female | |
|----------------------------------|--------------|--------------------------------|------------|------------|-------|--------------|-----------|------------|
| #Skin: Hemangioma | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/00 (0/0) | | 0/50 (0%) | 1/50 (2%) | 0/00 (0/0) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| #Skin: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (40/) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| O | Tatal | 0/50 (0%) | 2/50 (4%) | CD 4 040/ | Tatal | 2/50 (4%) | 0/50 (0%) | CD 4.700/ |
| Overall Incidence | Total | 3/200 (1.5%) | Mean 1.5% | SD 1.91% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.79% |
| #Skin: Liposarcoma | | | | | | | | |
| • | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| tSkin: | | | | | | | | |
| Myxosarcoma | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/00 (0/0) | | 0/50 (0%) | 0/50 (0%) | 0/00 (0/0) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| 1014- | | | | | | | | |
| #Skin: Neurofibrosarcoma or S | chwannoma (ı | malignant or NOS) 0/50 (0%) | | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/00 (0/0) | | 0/50 (0%) | 0/50 (0%) | 0/30 (0/0) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 243

Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

| | | | Male | | | | Female | |
|--|------------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| #Skin: Neurofibrosarcoma, Neurof malignant or NOS) | ibroma, or | Schwannoma (benign, | | | | | | |
| , | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| #Skin: Osteosarcoma | | | | | ••••• | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| #Skin: Sarcoma | | | | | ••••• | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 1/50 (2%) | 1/50 (2%) 0/50 (0%) | 2/50 (4%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 4/250 (1.6%) | Mean 1.6% | SD 1.67% |
| #Skin: Schwannoma Malignant | • | | | | ••••• | ••••• | ••••• | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| #Skin: Squamous Cell Carcinoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

nt System Page: 244
of Animal Groups Report Date: 04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

| | | | Male | | | | Female | | | |
|---|--------------|-------------------------|----------------------|-----------|-------|-------------------------|------------------------|-----------|--|--|
| #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | | |
| Skin: Squamous Cell Papilloma | | | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | | |
| Skin: Squamous Cell Papilloma | or Papilloma | ····· | | | | | | | | |
| oquamous son r upmoma s | . | 0/50 (0%) | 0/50 (00/) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | |
| verall Incidence | Total | 0/50 (0%) 0/200 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) 0/250 (0%) | 0/50 (0%) Mean 0% | SD 0% | | |
| Skin: | Davillama | C | | ••••• | | | ••••• | ••••• | | |
| Squamous Cell Papilloma, Carcinoma or Keratoacantl | | Squamous Cell | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | | |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | | |
| Skin: Squamous Cell Papilloma, | Papilloma, | or Keratoacanthoma | | | | | | | | |
| | • • | 0/50 (0%) | 0/50 (00/) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

| | | | Male | | | | Female | |
|---|-------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| #Skin: Trichoepithelioma | | | | | | | | |
| - | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| #Skin: Sebaceous Gland: Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| #Skin: Sebaceous Gland: Carcinoma | | | | | ••••• | | | |
| | | 0/50 (0%) 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| #Skin: Sebaceous Gland: Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| #Spinal Cord: Meningioma Malignant | | | | | ••••• | | | |
| | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL

Contract/Lab: All Laboratories

Strain: B6C3F1 Vehicle: FEED Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--------------------------------------|--------|--------------------------------------|------------------------|--------------------|-------|--------------------------------------|-----------------------------------|--------------------|
| *Spleen: Fibrous Histiocytoma | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/49 (0%) | 0/48 (0%) 0/50 (0%) | 0/48 (0%) |
| Overall Incidence | Total | 0/199 (0%) | Mean 0% | SD 0% | Total | 0/245 (0%) | Mean 0% | SD 0% |
| *Spleen: Hemangioma | •••••• | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/48 (0%) | 0/48 (0%) |
| Overall Incidence | Total | 0/49 (0%) 0/199 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/49 (0%) 0/245 (0%) | 0/50 (0%) Mean 0% | SD 0% |
| *Spleen: Hemangiosarcoma | | 0/50 (0%) | | 1/50 (2%) | | 2/50 (4%) | 1/48 (2%) | 1/48 (2%) |
| Overall Incidence | Total | 0/49 (0%) 3/199 (1.51%) | 2/50 (4%) Mean 1.5% | SD 1.91% | Total | 2/49 (4%) 6/245 (2.45%) | 0/50 (0%) Mean 2.45% | SD 1.68% |
| *Spleen: Mast Cell Tumor Malignar | nt | 0/50 (00/) | | 0/50 (00/) | | 0/50 (00/) | 0/40 /00/ | 0/40 /00/ |
| Overall Incidence | Total | 0/50 (0%) 0/49 (0%) 0/199 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/49 (0%) 0/245 (0%) | 0/48 (0%) 0/50 (0%) Mean 0% | 0/48 (0%) SD 0% |
| *Spleen: Plasma Cell Tumor Maligr | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/49 (0%) 0/199 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/49 (0%) 0/245 (0%) | 0/48 (0%) 0/50 (0%) Mean 0% | 0/48 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 247

| | | | Male | | | | Female | | | |
|--|-------|-------------------------|----------------------|-----------|-------|---------------------------|------------------------|-----------|--|--|
| #Stomach, Forestomach: Mast Cell Tumor Malignant | | | | | | | | | | |
| | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | | |
| verall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% | | |
| Stomach, Forestomach: Squamous Cell Carcinoma | | | | | | | | | | |
| | | 0/50 (0%) 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% | | |
| Stomach, Forestomach: Squamous Cell Carcinoma c | • | 2/50 (4%) 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | Total | 0/50 (0%) 2/50 (4%) | 0/50 (0%) 1/50 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 3/200 (1.5%) | Mean 1.5% | SD 1.91% | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.79% | | |
| Stomach, Forestomach: Squamous Cell Papilloma | | 2/50 (4%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) 2/200 (1%) | 0/50 (0%) Mean 1% | SD 2% | Total | 2/50 (4%) 3/250 (1.2%) | 1/50 (2%) Mean 1.2% | SD 1.79% | | |
| | | , | | | | ` , | | | | |
| Stomach, Glandular: Adenoma | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/30 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/30 (0%) | | |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Control Animal Groups Report Date:04/29/2009

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| | | | Male | | | | Female | |
|--|-------|-------------------------|----------------------|------------|--------|-------------------------|------------------------|-----------|
| #Stomach, Glandular: Carcinoma | | 0/50 (00/) | | 0/50 (00/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (00) |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| #Stomach, Glandular: Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/30 (0%) | Mean 0% | SD 0% |
| | | | | | ••••• | | | |
| *Testes: Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | | | |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | | | | |
| *Testes: | | | | | ••••• | | | |
| Hemangiosarcoma | | 0/50 (0%) | | 0/50 (0%) | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | | |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | | | | |
| *Thymus: | | | ••••• | | | | | |
| Thymoma Benign | | 0/41 (0%) | 244- (224) | 0/44 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/48 (0%) 0/178 (0%) | 0/45 (0%) Mean 0% | SD 0% | Total | 0/49 (0%) 0/246 (0%) | 0/49 (0%) Mean 0% | SD 0% |
| Overall Illiciaetice | IUIAI | 0/1/0 (0/0) | IVICALI U/0 | 3D 0/0 | i Ulai | 0/240 (0/0) | IVICALI U/0 | 3D 070 |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 249 Report Date:04/29/2009

Contract/Lab: All Laboratories

Route: ORAL

Strain: B6C3F1 Vehicle: FEED Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|----------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| *Thymus: Thymoma Malignant | | | | | | | | |
| | | 0/41 (0%) 0/48 (0%) | 0/45 (0%) | 0/44 (0%) | | 0/49 (0%) 0/49 (0%) | 0/50 (0%) 0/49 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/178 (0%) | Mean 0% | SD 0% | Total | 0/246 (0%) | Mean 0% | SD 0% |
| Thymus: Thymoma: Benign, Malign | ant, NOS | | | | | | | |
| | | 0/41 (0%) 0/48 (0%) | 0/45 (0%) | 0/44 (0%) | | 0/49 (0%) 0/49 (0%) | 0/50 (0%) 0/49 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/178 (0%) | Mean 0% | SD 0% | Total | 0/246 (0%) | Mean 0% | SD 0% |
| Thyroid Gland: Adenoma | | | | | | ••••• | | |
| | | 0/50 (0%) 0/50 (0%) | 0/48 (0%) | 0/50 (0%) | | 0/50 (0%) 1/50 (2%) | 0/48 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/198 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% |
| Thyroid Gland: C-Cell: Carcinoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/48 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/48 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/198 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% |
| Thyroid Gland: C-Cell: Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/48 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/48 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/30 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Thyroid Gland: Follicular Cell: Adenoma 0/50 (0%)(2%)1/50 (2%)0/48 (0%)(0%)(2%)(0%)1/50 0/48 (0%)0/50 0/50 (0%)2/198 (1.01%) **Overall Incidence** Total Mean 1% SD 1.15% Total 1/248 (0.4%) Mean 0.4% SD 0.89% *Thyroid Gland: Follicular Cell: Carcinoma 0/50 (0%)0/50 (0%)0/48 (0%)(0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/248 (0%) Mean 0% SD 0% 0/198 (0%) *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma 0/50 (0%)1/50 (2%)0/48 (0%)0/50 (0%)1/50 (2%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/198 (1.01%) Mean 1% SD 1.15% Total 1/248 (0.4%) Mean 0.4% SD 0.89% **#Tissue NOS:** Carcinoma 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Mean 0% SD 0% Total 0/200 (0%) Mean 0% Total 0/250 (0%) **#Tissue NOS:** Hemangiosarcoma 0/50 (0%)0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%)Mean 0% SD 0% Total 1/250 (0.4%)Mean 0.4% SD 0.89%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: FEED

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| | | | Male | | | | Female | |
|---|-------|------------------------|-----------|-----------|-------|------------------------|------------------------|-----------|
| Tissue NOS: Plasma Cell Tumor Malign | ant | | | 2/20 (00) | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Fissue NOS: Schwannoma Malignant | | | | | | | | |
| | | 0/50 (0%) 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/200 (0.5%) | Mean 0.5% | SD 1% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Tongue: Fibroma | | | | | ••••• | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Tongue: | | | | | | | | |
| Squamous Cell Carcinoma | 3 | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | , , | | 0/50 (0%) | 0/50 (0%) | , , |
| verall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Tongue: Squamous Cell Carcinoma | | | | | | | | |
| - 4 | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 252 Report Date: 04/29/2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

| | | | Male | | | | Female | |
|--|-------|------------------------|-----------|------------|-------|------------------------|------------------------|-----------|
| Tongue: Squamous Cell Papilloma | | 0/50 (00/) | | 0/50 (00/) | | 0/50 /00/ | 0/50 (00/.) | 0/50 /00/ |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Tooth: Odontoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/200 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| Urinary Bladder: Hemangioma | | | | | | | | |
| Ū | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/49 (0%) |
| verall Incidence | Total | 0/199 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% |
| Jrinary Bladder: Hemangiosarcoma | | | ••••• | | | ••••• | | |
| nemangiosarcoma | | 0/50 (0%) | | 0/49 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | |
| verall Incidence | Total | 0/199 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% |
| Urinary Bladder: Plasma Cell Tumor Malign | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/199 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

| | | | Male | | | | Female | |
|------------------------------|-------|------------------------|-----------|-----------|---|------------------------|------------------------|-----------|
| *Urinary Bladder: Sarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/199 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% |
| #Uterus: Adenoma | | | | ••••• | | | | |
| | | | | | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | | | | | Total | 0/250 (0%) | Mean 0% | SD 0% |
| #Uterus: Carcinoma | | | | | | | | |
| Garcinoma | | | | | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | | | | | Total | 0/250 (0%) | Mean 0% | SD 0% |
| #Uterus: | | ••••• | | ••••• | • | | | |
| Hemangioma | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | | | | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | | | | | Total | 0/250 (0%) | Mean 0% | SD 0% |
| | | | | | ••••• | | | |
| #Uterus: Hemangiosarcoma | | | | | | | | |
| | | | | | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | | | | | Total | 0/250 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

| | Male | | Female | |
|----------------------------------|-------|---|----------------------------------|-------------|
| #Uterus: | | | | |
| Leiomyoma | | 0/50 (0%) | 1/50 (2%) 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% SD 0.89% | |
| | | • | | • • • • • • |
| #Uterus: Leiomyosarcoma | | | | |
| | | 2/50 (4%) | 0/50 (0%) 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% SD 1.79% | |
| | | | | •••• |
| #Uterus: Polyp Stromal | | | | |
| . M | | 2/50 (4%) | 0/50 (0%) 2/50 (4%) | |
| | | 0/50 (0%) | 4/50 (8%) | |
| Overall Incidence | Total | 8/250 (3.2%) | Mean 3.2% SD 3.35% | |
| | | | | • • • • • • |
| #Uterus: Sarcoma Stromal | | | | |
| Sarcoma Stromai | | 0/50 (0%) | 0/50 (0%) 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% SD 0% | |
| | | | | |
| #Uterus: | | | | |
| Sarcoma Stromal or Polyp Stromal | | 2/50 (40/) | 0/50 (00/) 2/50 (40/) | |
| | | 2/50 (4%) 0/50 (0%) | 0/50 (0%) 2/50 (4%) 4/50 (8%) | |
| Overall Incidence | Total | 8/250 (3.2%) | Mean 3.2% SD 3.35% | |
| | | , | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Schwannoma Malignant 1/50 (2%)0/50 (0%)(0%)(2%) (0%)1/50 0/50 **Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.1% #Vagina: Squamous Cell Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Vagina: Squamous Cell Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 Mean 0% #Zymbal's Gland: Carcinoma 0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)1/50 (2%)0/50 (0%)**Overall Incidence** SD 0% SD 0.89% Total 0/200 (0%) Mean 0% Total 1/250 (0.4%) Mean 0.4% #Zymbal's Gland: Carcinoma or Adenoma 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/200 (0%)Mean 0% SD 0% Total 1/250 (0.4%)Mean 0.4% SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied